ENDOTEC

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March 25, 2005

Division of Dockets Management
FDA
5630 Fishers Lane
Room 1061 (HFA-305)
Rockville, MD 20852

**Re: Docket Number 2004P-0457/CCP 1: Reclassification of Non-constrained, Mobile-Bearing Ankle Prosthesis: Comments on the Comments in Opposition to Reclassification Petition**

Dear Sir or Madam:

The comments of January 10, 2005 need to be addressed so as to more fully understand their significance. This letter is an attempt to do so.

**I.** In their introduction Hogan & Hartson (H&H) state that "the use of total ankle replacement prostheses raises safety concerns that can only be addresses adequately through the premarket approval ("PMA") process." This statement suggests that a reclassification of ankle devices is inappropriate. If the FDA had taken such a position we would, of course, not have submitted a reclassification petition.

The FDA has, however, found that some ankle devices are reasonably safe and thus has classified some ankle configurations as class II. A reclassification to include newer designs is therefore appropriate. The original findings on ankle classification in 1982 are based on data from a quarter of a century ago. This petition reviews this data and the larger amount of data that has been accumulated during the last quarter century.

H&H then go on to state "clinical data on the use of prostheses such as the B-P ankle have only recently begun to emerge." This is simply not true from any reasonable understanding of the words "only recently". This can be clearly seen if one examines the literature cited in the petition. Although there has been a recent acceleration in the availability of literature on such ankles it is because after a long period of clinical use the use of such devices has accelerated outside the USA.

**II.** H&H present only an, unsupported, subjective opinion on this matter. The FDA will decide if this opinion is correct.

**III.A** In evaluating the question as to how much and what quality clinical evidence is sufficient it should be noted that the evidence presented in this petition is clearly superior to the clinical evidence on which the classification of 1982, which this petition seeks to modify, was based. The standard for sufficiency is not an absolute standard. It is a relative standard. Thus the question here is: Is it clear from the available evidence that devices

2004P 0457 C2

**B.** The merits and deficiencies of the mechanical testing associated with this petition should be addressed by competent scientific and engineering personnel (which I am sure they will be) when this position goes before a panel. It should be noted that the long clinical use of such devices speaks more adequately has to their safe performance than any test program that one may reasonable devise. Thus it seems difficult to rationalize rejecting this petition for testing that seems clearly unneeded. What would one expect to find from such testing that has not already been found from the long-term clinical use of such devices?

It should be noted that the FDA has not asked for any additional testing before approving the clinical trial of the B-P ankle device.

**C.** The "Agility" is a currently available device and as far as we know the only one available in the USA. Its existence and use are, in our opinion, a strong reason for reclassification. The success and proliferation of the B-P type ankle device and the poor results and lack of acceptance of the Agility is a strong reason to provide US surgeons with a viable alternative to the Agility. A failure to reclassify will mean that American citizens will be denied the most widely used type of ankle replacement and subject them to the use of one with poor clinical performance.

**IV.** H&H set an unreasonable standard that is inconsistent with long established FDA standards. The "preliminary" studies they refer to are of a much longer duration than those required by the orthopaedics department of the FDA for their clinical trials. If the arguments and the standards used by H&H are appropriate it is doubtful that any prosthetic device should be 510K cleared.

It should be noted that the reclassification petition primarily seeks to address the deficiency in the current classification that, as interpreted by the FDA, requires mechanical constraint even where physiological constraints are present. The data presented in the petition is clearly sufficient to show that mechanical constraints are not needed where the normal physiological constraints are present. Thus the classification criterion should be changed to allow the inclusion of physiological constraints in the determination of semi-constraint for the purpose of classification.

Sincerely

*Michael J. Pappas*

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